UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,858	12/12/2005	Daniel Raederstorff	21478USWO (C038435/0187	7897

7590 07/11/2007

Bryan Cave
1290 Avenue of the Americas
New York, NY 10104

EXAMINER	
MCCORMICK, MELENIE LEE	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,858	RAEDERSTORFF ET AL.	
	Examiner	Art Unit	
	Melenie McCormick	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *25-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendments with remarks filed 17 April 2007 have been received and considered.

Claims 1-24 have been cancelled. New claims 25-55 have been added.

Claims 25-55 are presented for examination on the merits.

Please note that claim 49 is missing. Claim 48 is followed by claim 50.

Claim Rejections - 35 USC § 112

The previous rejection of claims 1-13, 20 and 24 under 35 U.S.C. 112, first paragraph, has been withdrawn in view of Applicants amendments.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The previous claims rejected under obvious-type double patenting have been cancelled, therefore the previous rejections have been withdrawn. The newly added claims rejected under obvious-type double patenting are presented below.

Claims 46-47, 50, 52-53, and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-13 of copending Application No. 10/766,118. Although the conflicting claims are not identical, they are not patentably distinct because each are drawn to a method of treating non-insulin dependent diabetes comprising administering to a subject in need a composition which comprises phytanic acid.

Claims 25-50 and 52-55 are provisionally rejected as being unpatentable over claims 8-18 of copending Application No. 10/573,222 because each are drawn to a nutraceutical composition for the treatment or prevention of diabetes comprising phytanic acid and EGCG and a method of treating diabetes using this composition.

Claims 25-45 are provisionally rejected as being unpatentable over claims 1-8 of copending Application No. 10/558,042 because each are drawn to compositions comprising EGCG.

Claims 25-47 and 50-55 are rejected as being unpatentable over claims 1-9 of copending Application No. 10/536,374 because both are drawn to a composition

comprising EGCG for treatment of diabetes, a method of making the composition and a method of treatment of diabetes using the composition.

Claims 25-55 are rejected as being unpatentable over claims 1-8, 18-20 and 26-27 of copending Application No. 10/525,348 because each are drawn to a composition comprising at least one of EGCG, phytanic acid, pantethine, lipoic acid and policosanol and a method for the treatment of diabetes comprising administering to a subject in need thereof such a composition.

Further, please note that the claims of '118, '222, 042, '374, '348 encompass and/or are encompassed by the instant claims.

The above rejections are provisional obvious-type double patenting rejections because the conflicting claims have in fact not been patented.

Claim Rejections - 35 USC § 102

The previous claims rejected under 35 U.S.C. 102(b) have been cancelled, thus the rejection of these claims has been withdrawn.

The rejection of the new claims is presented below.

Claims 42-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorsek (US 6,565,896).

A composition comprising EGCG and pantethine is claimed.

Gorsek teaches a composition which comprises EGCG and pantethine (see e.g. claim 1).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (i.e. as a treatment for diabetes, obesity or glucose intolerance), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Therefore, the reference is deemed to anticipate the instant claims above.

Applicant's argue that because claims 1-2 have been cancelled, the rejection of the claims under 102(b) over Gorsek, which teaches a composition comprising EGCG and pantethine is moot. The previous rejection of claims 1-2 has been withdrawn in view of the cancellation of the claims, however, new claims 42-44 are drawn to a composition comprising EGCG and pantethine and are therefore rejected under 35 U.S.C. 102(b) as being anticipated by Gorsek.

The rejection is deemed proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan (US 5,922,756), Fluehmann et al. (US 6,784,207), and Cincotta et al. (US 5,714,519) for reasons et forth in the previous Office Action which are restated below.

A composition comprising EGCG and at least one of pantethine and phytanic acid, a method of making the composition, and a method of treatment of type I and type II diabetes comprising administering to a subject in need thereof a composition comprising EGCG and pantethine and phytanic acid is claimed.

Chan beneficially teaches that EGCG is an inhibitor of nitric oxide synthase (see e.g. col. 3, lines 23-25). Chan further teaches that an NO synthase may be involved in diabetes and therefore, catechin derivative (including EGCG) may be helpful in treating the condition (see e.g. col 3, lines 51-56). Chan also beneficially teaches a method of treating diabetes which comprises administering to a mammal in need thereof EGCG (See e.g. claims 1, 2, and 7). Chan further teaches that EGCG is in a pharmaceutical formulation presented in discrete unit dosages and that the discrete unit dosages may be capsules or tablets (solid unit dosages) (see e.g. col 4, lines 18-34). Chan also teaches that the EGCG is administered in a dose of 50 mg to 17.5 grams/day, which is within the dose range instantly claimed (see e.g. claim 6). Chan does not explicitly teach that phytanic acid or pantethine are included in this composition.

Fluehmann et al. beneficially teach a composition for the treatment of diabetes comprising phytanic acid, a method of making the composition (see e.g. col 6, lines 1-5) and a method for the treatment of diabetes using phytanic acid (see e.g. col 1, lines 11-15). Fluehmann et al. also beneficially teach that the composition is in a unit dosage form, such as tablets or capsules (solid dosage forms) (see e.g. col 7, lines 57-61). Fluehmann et al. further teach that the amount of phytanic acid administered is within the dose range instantly claimed (about 0.1 to about 1000 mg, about 0.1 to about 500 mg or about 0.1 to 100 mg) (see e.g. claims 1, 4 and 5).

Cincotta et al. beneficially teach a method for the treatment of diabetes comprising administering to a subject in need thereof an effective amount of pantethine (see e.g. col 4, lines 26-34). Cincotta et al. also disclose that the dose range intended for use with this method is between 15 to about 500 mg/kg of body weight per day, which is within the dose range instantly claimed (see e.g. col 5, lines 6-11 and claim 5).

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to admix EGCG, pantethine, phytanic acid and mixtures thereof in the dosage forms and amounts instantly claimed in order to make a composition for the treatment of diabetes. One of ordinary skill in the art would have been motivated to so based upon the disclosures of Chan, Fluehmann et al., and Cincotta et al. that EGCG, phytanic acid and pantethine are useful in the treatment of diabetes in the same ranges of dose amounts and in the same forms instantly claimed. It would further have been obvious to administer such a composition to a subject in need of treatment for diabetes, especially in view of the disclosure of methods for

treatment disclosed by Chan, Fluehmann et al., and Cincotta et al. which comprise administration of each component of the instantly claimed composition to a subject in need of diabetes treatment. The adjustment of particular conventional working conditions (e.g. the particular result effective amounts of each component within the composition and the addition of the composition to a food or beverage) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would recognize that since Chan, Fluehmann et al., and Cincotta et al. teach that EGCG, phytanic acid and pantethine are useful in the treatment of diabetes, it would be advantageous to combine them for the same purpose.

Applicants also argue that because Chan et al. discloses that EGCG may be useful in treating inflammatory conditions and provide type I diabetes as an example, that it would defy common sense to combine EGCG with the other components of the instantly claimed composition and method of using the composition. Applicants argue that because Fluehmann et al. and Cincotta et al. teach that phytanic acid and

pantethine are useful for treating type II diabetes and Chan et al. mentions treating type I diabetes with EGCG, it would be self defeating to combine these components for treatment of both type I and type II diabetes. Applicants have, however, combined these components for this same purpose (see e.g. claims 48 and 50). If, at the time the instant Application was filed, it would have been futile to combine the components in order to treat both type I and type II diabetes, Applicants invention would not be enabled. Applicants have summarized the teachings of Chan et al., Fluehmann et al. and Cincotta et al. and have suggested possible mechanisms by which each of the disclosed treatments for diabetes using EGCG, phytanic acid and pantethine may act. These arguments are not persuasive, however, as these mechanisms are not explicitly disclosed by the references. Treating diabetes, however, is disclosed by Chan et al. (see e.g. claim 2), Fluehmann et al. (see e.g. abstract) and Cincotta et al. (see e.g. col 5, lines 5-10). Please note also that Cincotta et al. teach that patients of both type I and type II diabetes may share the problem of insulin resistance (see e.g. col 1, lines 47-56). Therefore, one of ordinary skill in the art at the time the claimed invention was made would recognize that both conditions may benefit from similar treatment methods.

Therefore, the rejection is deemed proper and is maintained.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan (US 5,922,756), Fluehmann et al. (US 6,784,207), Cincotta et al. (US 5,714,519), Fischer (US 5,599,835), Pistolesi (WO 02/052955 A1) and Eriksson et al. (BioFactors) for reasons set forth in the previous Office Action, which are restated below.

Chan (US 5,922,756), Fluehmann et al. (US 6,784,207), and Cincotta et al. (US 5,714,519) beneficially teach compositions and methods for the treatment of diabetes comprising EGCG, phytanic acid and pantethine and are relied upon for the reasons set forth above.

Fischer (US 5,599,835) beneficially teaches lipoic acid as a treatment for diabetes (see e.g. abstract). Fischer further teaches a method for the treatment of diabetes comprising administering to a person in need thereof an effective amount of a medicinal food comprising lipoic acid (see e.g. claim 1).

Pistolesi beneficially teaches a composition for treating aging processes and related compositions, including diabetes. Pistolesi further teaches that the composition comprises policosanol (see e.g. page 1). Pistolesi also discloses that the composition may be used in functional foodstuffs (see e.g. claim 19).

Eriksson beneficially teaches the use of coenzyme Q_{10} in a treatment for diabetes (see entire document and Discussion).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the ingredients beneficially taught by Chan, Fluehmann et al., Cincotta et al., Fischer, Pistolesi, and Eriksson to make a food or beverage comprising EGCG, pantethine, phytanic acid, lipoic acid, policosanol and coenzyme Q_{10}. A person of ordinary skill in the art would have been motivated to combine these ingredients because, as discussed above and in the instantly cited references, the use of these compounds for the same purpose (treatment of diabetes) was known at the time the claimed invention was made. A person of ordinary skill in the

art would have further been motivated to add the composition to a food or beverage since this is a widely known modification in the nutritional supplement art and since it is disclosed by Fischer and Pistolesi that a diabetes treatment is in the form of a food.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants arguments concerning Chan et al., Fluehmann et al., and Cincotta et al. are discussed above. Applicants argue that it would not be obvious to further add, lipoic acid, policosanol and coenzyme Q_{10} to a composition in order to treat diabetes as instantly claimed. This is not persuasive, however, as Fischer, Pistolesi, and Eriksson each teach that lipoic acid, policosanol and coenzyme Q_{10} are useful in treating diabetes. Therefore one of ordinary skill in the art would be motivated to combine these components with others that are known in the art to be useful for treating diabetes in order to form a food supplement which is useful in treating diabetes.

The rejection is deemed proper and is maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick
Examiner
Art Unit 1655

CHRISTOPHER R. TATE
PRIMARY EXAMINER